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No. 92-___

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

JANE KING,
Petitioner,

v.

THE COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, that bars states from "establishing or continuing in effect" device requirements that are "different from, or in addition to" a requirement under the MDA, preempts all state-law damage claims against a manufacturer of a medical device approved for marketing by the Food and Drug Administration ("FDA") where:

> (1) there are no specific federal regulatory requirements for the device in question that coincide with petitioner's state law claims, and (2) the FDA's own view is that the MDA does not preempt damage claims.

PARTIES TO THE PROCEEDINGS

In addition to petitioner Jane King and respondent Collagen Corporation, who appeared as appellant and appellee, respectively, in the court of appeals, the Association of Trial Lawyers of America and the Health Industry Manufacturers Association appeared as *amici curiae* in the court of appeals.

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In The

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No. 92-___

JANE KING,

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the United States Court of Appeals for the First Circuit is reported at 983 F.2d 1130 (1993), and is reproduced in the appendix at 1a-21a. The unreported decision of the United States District Court for the District of Massachusetts is reproduced in the appendix at 22a-23a.

JURISDICTION

The judgment of the court of appeals was entered on January 15, 1993. Petitioner filed a timely petition for rehearing on January 29, 1993, which was denied by the court of appeals on February 3, 1993 (24a). On April 26, 1993, Justice Souter granted petitioner's application for an extension of time to file this petition for a writ of certiorari up to and including June 23, 1993. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this

section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

STATEMENT OF THE CASE

In what the former Chief Counsel to the Food and Drug Administration ("FDA") has called "probably the single most important case to the medical-device industry in American history,"[1] the court of appeals has held that the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, preempt all damages claim against a medical device manufacturer on the ground that Congress intended the

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[1] Edward Felsenthal & Lee Berton, *FDA Approval Shields Firms in Injury Suits*, Wall St. J., Jan. 21, 1993, at B1 (quoting Peter Hutt, former FDA Chief Counsel).

FDA's marketing approval for the device to insulate the manufacturer from state-law liability. The court of appeals erred because the MDA's express preemption language, 21 U.S.C. § 360k(a), applies only to situations where there is a counterpart federal regulation or a provision of the MDA specifically applicable to a particular device, and because that language applies only to state and local positive enactments, not damage claims. These conclusions are in accord with regulations of the FDA, the federal agency specifically charged with implementing and interpreting the MDA.

Furthermore, as the court of appeals acknowledged (18a), the decision below posits that Congress intended to leave injured patients without any remedy against the manufacturers of Class III medical devices -- devices that are the most likely to cause serious injury to consumers. *See* 21 U.S.C. § 360c(a)(1)(C). Under the First Circuit's reasoning, Congress deliberately intended to displace the tort system and deprive consumers of a remedy, regardless of the severity of the injury or the theory of liability alleged, including the manufacturer's fraud in obtaining device approval from the FDA. The First Circuit came to this conclusion, even though Congress did not say a word about preempting common law actions and did not provide an alternative compensation system. Review is also warranted because the lower federal courts and state courts are deeply divided over the preemptive scope of the MDA, including the precise issue presented in this petition, and because the decision of the court of appeals is at odds with this Court's Supremacy Clause jurisprudence, particularly with the Court's recent decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992).

1. *Facts and Procedural Background.* In May 1987, petitioner Jane King was injected with a test dose of Zyderm, a medical device manufactured by respondent Collagen Corporation. Zyderm treatment consists of injecting processed cow tissue under the skin, which is supposed to correct wrinkles and other skin deformities by bolstering the skin from below (2a). Shortly after receiving the test dose, but before undergoing the full treatment, petitioner began suffering from extreme weakness and pain in her muscle joints, particularly in her legs, arms, and neck (3a).

Compl. ¶ 6 (A00007).[2] Petitioner maintained that the test dose of Zyderm caused her to suffer from polymyositis or dermatomyositis ("DM/PM"), autoimmune diseases that cause the immune system to attack skin and muscle tissue as if they were foreign substances, rendering petitioner permanently and totally disabled. *Id.* ¶ 7.

In October 1990, petitioner filed her complaint in Massachusetts Superior Court, alleging that Zyderm was labeled, promoted, and sold with inadequate warnings of possible adverse reactions and no warnings about autoimmune diseases such as PM/DM. *Id.* ¶¶ 10-11 (A00008). Petitioner also maintained that respondent knew or should have known that Zyderm likely caused DM/PM, but nevertheless failed to warn her, and further engaged in an active campaign to suppress the facts, blame the disease on other causes, and to prevent discovery of the risks associated with Zyderm. *Id.* ¶¶ 12-13. The alleged campaign of fraud and misrepresentation extended to efforts to deceive patients, their doctors, and the FDA during the device approval process. Amd. Compl. ¶¶ 9, 12 (A00029, A00030).[3]

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[2] References beginning with "A" refer to respondent's Record Appendix filed in the court of appeals.

[3] Respondent moved for summary judgment on preemption grounds, and thus neither the court nor the jury heard petitioner's evidence (A00033). Petitioner maintained that respondent failed to warn of DM/PM, although it could have done so (A00464), and that respondent knew of the DM/PM association for many years but did not specifically warn of it until the FDA and others unearthed the information (A00483). Among other things, petitioner specifically maintained that respondent withheld information by failing to file with the FDA legally-required reports of adverse reactions (A00479), by publishing misleading pamphlets and "Dear Doctor" letters (*id.*), and by falsely trumpeting the significance and extent of FDA approval of its product (A00483). Petitioner also proffered expert testimony that the original 1981 FDA marketing approval for Zyderm was fraudulently obtained because of the way in which clinical data was presented and the withholding of pertinent information (A00491-A00514). *See also* A00515-00520 (describing FDA seizure of mislabeled Zyderm, and noting that, upon examination of more complete data, FDA took position that there may be a significant association between use of Zyderm and occurrence of PM/DM); Committee on Government Operations of the U.S. House of Representatives, *Is the FDA Protecting Consumers From Dangerous Off-Label Uses of Medical Drugs and Devices?* 22-28, 41 (GPO Nov. 19, 1992)(concluding that respondent

(continued...)

The original complaint alleged three counts. Count I set out respondent's negligence in failing to adequately test and manufacture Zyderm and in marketing the product, Count II claimed that respondent breached an implied warranty of merchantability and/or unlawfully sold a defective or dangerous product, and Count III alleged that petitioner's injuries were a result of respondent's deceit or fraud (A00009). Petitioner's Amended Complaint, filed on January 23, 1992 (Docket Entry 42, A00006), reorganized these allegations as claims for strict liability, breach of warranty, negligence, product misbranding and mislabeling, misrepresentation, failure to warn, and fraud (A00027-A00030).

On November 9, 1990, respondent removed the case to the United States District Court for the District of Massachusetts on the basis of diversity of citizenship (A00013), and filed an answer (A00015). After both parties were afforded discovery, respondent moved for summary judgment on the ground that petitioner's claims were preempted by the MDA (A00033), specifically by the FDA's 1981 decision to allow Zyderm to be marketed. In a two-page memorandum opinion (22a-23a), Judge A. David Mazzone granted respondent's motion for summary judgment, relying solely on a Texas case involving Zyderm in which summary judgment was granted to respondent on the basis of the FDA's marketing approval.[4] Thereafter, petitioner moved the district court to reconsider its decision. The court declined to do so because, by that time, the court of appeals had taken jurisdiction of the case, but Judge Mazzone noted that "[i]f I had authority, I would grant this motion to reconsider." Appellant's [First Circuit] Excerpts of Record, Ex. G.

2. *Decision of the Court of Appeals.*

The court of appeals affirmed in two separate opinions, one written by Judge Juan R. Tourrella and the other, labelled a

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[3](...continued)
mislabeled and misrepresented Zyderm and failed to make necessary reports to FDA, and discussing potential relationship between PM/DM and Zyderm).

[4] *See Stamps v. Collagen Corporation*, No. H-90-2242 (S.D. Tex. Oct. 11, 1991)(A00530-A00534), *aff'd*, 984 F.2d 1416 (5th Cir. 1993). A petition for a writ of certiorari will be filed in *Stamps* on or about June 16, 1993.

"concurring" opinion, but representing the panel majority, written by Senior Judge Bailey Aldrich, joined by Senior Judge Levin H. Campbell. We review each opinion in turn.

After briefly discussing the history and uses of Zyderm, Judge Tourrella turned to the MDA's pre-market approval process, noting that Zyderm was placed in Class III "for medical devices which are too dangerous or unknown to permit less regulation" (2a). Under that process, respondent was required to submit proposed labeling, testing data, and other information deemed pertinent by the FDA (*id.*), and the Agency retained the power to conduct various forms of post-market surveillance (3a), as it does with all devices.

After Zyderm was approved by the FDA, up to when petitioner fell ill after receiving her Zyderm injection in 1987, Judge Tourrella noted, use of the device was only contraindicated for users with a personal history of autoimmune disease (*id.*). By 1991, that contraindication had been removed from the labeling, but the FDA required in that year that respondent specifically warn that some patients, such as petitioner, had suffered an autoimmune response after Zyderm use.

Judge Tourrella reviewed the causes of action alleged in petitioner's amended complaint, and then considered what he viewed as the relevant legal background.[5] After reciting basic preemption principles (5a-6a), Judge Tourrella considered the MDA's preemption language, 21 U.S.C. § 360k(a), which provides that

> [N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable

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[5] The causes of action alleged in the amended complaint are discussed *supra* at 5-6. Although there was a dispute as to whether the amended complaint, rather than the original complaint, was the operative legal document, both panel opinions resolved that dispute in favor of the amended complaint (3a n.1, 14a), and, therefore, we look to that pleading as well.

to a device under this chapter.

Judge Tourrella then turned "for guidance" (7a) to the FDA's regulations on MDA preemption, 21 C.F.R. § 808.1, which recognize that preemption occurs only where the FDA has issued regulations, or the MDA itself creates requirements, specific to a particular device and a state has established different or additional statutory or regulatory requirements on the same subject matter. He then stated that federal law imposed requirements "on Zyderm related to labeling, design, manufacturing and other aspects of the device ... (7a)," without explaining the specific FDA requirements to which he was referring (8a), and without analyzing the FDA's regulations or regulatory commentary concerning the scope of MDA preemption. "Armed with this understanding" of the MDA's preemption provision (*id.*), 21 U.S.C. § 360k(a), Judge Tourrella analyzed the viability of petitioner's claims, rejecting each of them on preemption grounds.

As to strict liability, Judge Tourrella stated that, because the general purpose of MDA device approval is to ensure reasonable safety for users, petitioner's claim was preempted because it would impose requirements "related to ... safety and effectiveness" (8a) and require respondent to redesign its product. He did not point, however, to any specific FDA regulations or approval requirements relating to Zyderm design that conflicted with the strict liability claim.

Petitioner's implied warranty of merchantability claim was preempted because it arose by operation of state contract law, and thus would impose an additional requirement on respondent (10a). Here, again, Judge Tourrella did not explain what applicable FDA requirement was in conflict with petitioner's cause of action (*id.*). Similarly, Judge Tourrella rejected the negligence claims with respect to design, manufacture, sale, and marketing of Zyderm, noting that Class III devices are subject to regulation in those general areas, but not pointing to any specific FDA regulation of collagen implants on those particular matters (*id.*).

Turning to petitioner's misbranding claim (*id.*), Judge Tourrella maintained that it, too, was preempted because respondent's labeling accurately described the product, notwithstanding petitioner's allegations that the labeling understated Zyderm's risks and respondent's obligation to insure that its

labeling was neither false or misleading (*id.*, *citing* 21 U.S.C. § 352(a)). Similarly, in Judge Tourrella's view, the failure to warn and misrepresentation claims were preempted because they would have required that respondent's label read differently from the FDA-approved version, despite respondent's freedom to add safety warnings without FDA approval (11a), *see* 21 C.F.R. § 814.39(d)(1), and the fact that the misrepresentation claim relied on allegations of deceptive labeling and promotion of the product to petitioner's physician, not simply a duty to warn prospective users.

Finally, as to the fraud claim, Judge Tourrella held that, because petitioner's claim was, in his view, solely one under a Massachusetts statute requiring privity between buyer and seller, it was barred as a matter of state law (11a). However, he stated alternatively that the fraud count was preempted because it was a disguised failure to warn claim (*id.*), without addressing petitioner's allegation of respondent's fraud on the FDA in the marketing and approval of Zyderm.

After reviewing petitioner's causes of action and the MDA's legislative history (12a-16a), Judge Aldrich, joined by Judge Campbell, began with 21 U.S.C. § 360e(c)(1), the part of the MDA that describes the contents of a Class III pre-market approval application (16a-17a). In particular, Judge Aldrich looked to § 360e(c)(1)(F), which requires the applicant to submit proposed labeling to the FDA. Because the MDA requires that "labels be reviewed by the FDA," he said, "preemption ... is unavoidable ..." (18a). Judge Aldrich believed that this provision was critical, because, except for fraud, all of petitioner's causes of action -- such as misrepresentation, breach of implied warranty, and negligent design and testing -- were failure to warn claims (13a). This was so, in Judge Aldrich's view, because, had respondent warned petitioner that Zyderm might cause PM/DM, petitioner "would have no claim under any of these headings" (13a).

Judge Aldrich also noted that, under 21 C.F.R. § 814.39(d)(1), respondent could have changed its labeling to add warnings without FDA approval, but held that provision of no significance since it is not mandatory (18a). He did not explain, however, why a state warning claim to enhance safety under such

circumstances would be "different from or in addition to" the federal scheme. The opinion also acknowledged petitioner's argument that the FDA's preemption regulations, 21 C.F.R. § 808.1(d), would allow her claims to go forward, but dismissed that point by stating that "[w]hen a statute is clear the agency interpretation must give way" (18a).

Finally, Judge Aldrich addressed the "more troublesome issue" of fraud (*id.*), particularly as it applied to petitioner's allegation that Zyderm's approval itself was procured through deception of the FDA (19a). While acknowledging a conflict with *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988), he held that whether there has been fraud on the FDA was a determination to be made by the Agency, not a jury (20a). Moreover, in Judge Aldrich's view, petitioner's claim of misrepresentation based on statements made to the public and petitioner's physician was also preempted because those statements were "approved by the FDA ..." (21a n.8). Judge Aldrich did not refer, however, to a particular substantive federal requirement pertaining to Zyderm that conflicted with petitioner's state-law fraud or misrepresentation claims.

REASONS FOR GRANTING THE WRIT

The FDA -- the agency charged by Congress with implementing and interpreting the MDA -- has consistently maintained that the preemptive effect of 21 U.S.C. § 360k(a) is confined in two related respects. First, it believes that § 360k(a) does not oust state law unless the FDA has established, or the MDA itself contains, specific requirements with respect to a particular device, and the state has established specific different or additional requirements applicable to the same aspect of that particular device. *See, e.g.*, 21 C.F.R. § 808.1(d). Second, the FDA has concluded that § 360k(a) does not apply at all to duties created under state tort and contract law that are intended to compensate injured consumers, because those duties are of "general applicability where the purpose of the requirement relates ... to other products in addition to devices ... ." *Id.* § 808.1(d)(1).

In this case, the First Circuit issued two opinions, one which purports to rely on the FDA's views (7a), but fails even to cite the most relevant of those views, and the other which dismisses the FDA's interpretations in one sentence (18a),

apparently on the ground that they are inconsistent with the statute. As a result, the First Circuit's ruling conflicts with the language of the MDA, the FDA's interpretation of that language, decisions of other state and federal courts, and this Court's ruling in *Cipollone*. In addition, the court of appeals' reasoning sweeps so broadly that not only petitioner, but *all* patients who are injured by Class III medical devices -- devices that are the most dangerous and likely to cause injury -- would be left without a remedy.

A. Review Should be Granted Because the Ruling of the Court of Appeals is Inconsistent with (1) the Language of the MDA and the Authoritative Regulations of the FDA, (2) Decisions of Other Federal and State Courts, and (3) This Court's Ruling in *Cipollone*.

Before turning to the MDA's preemption provision, it is important to review four bedrock principles applicable to this case that were largely overlooked by the court of appeals. First, because of the importance of preserving our delicate state-federal balance, *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985), there is a strong presumption against preemption that may only be overcome by "clear and manifest" Congressional intent to oust state and local law. *See Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2482, 2485 (1991). Second, this powerful presumption is even stronger where, as here, preemption would displace the historic power of the state to protect the health and safety of its citizenry. *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Third, where a finding of preemption of common law claims would leave injured consumers without *any* state *or* federal remedy, as concededly is the case here (18a), this Court ascribes preemptive intent to Congress only in the most compelling circumstances. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). Finally, in the preemption context, as in others, the views of the agency charged with administering the statutory scheme are entitled to deference, *Hillsborough County*, 471 U.S. at 714, which is important here because, as we explain below, the FDA's views of MDA preemption are flatly at odds with the result reached by the court of appeals.

1. *The Language of the MDA and the FDA's Regulations.* With these principles in mind, we turn to the MDA's

preemption provision:

> [N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under this chapter.

21 U.S.C. § 360k(a).

This language does not preempt all state-imposed forms of liability that relate to the safety and effectiveness of a device subject to the MDA, as, in essence, the court of appeals held. Rather, state device requirements are preempted only if they are requirements "with respect to a device" and are "different from, or in addition to" pre-existing federal requirements that concern that particular device's safety and effectiveness. Thus, even if § 360k(a) applies to common law damage actions, which petitioner and the FDA dispute (*see infra* Part B), petitioner's claims, based on the inadequate design and testing of Zyderm, the manufacturer's failure to warn, breach of implied warranty, misrepresentation, and fraud, would be preempted under § 360k(a) only if there are federal requirements imposed upon collagen implants regarding those subject matters. Here, however, there are no warnings required by regulation, nor are there specific regulations or statutory provisions requiring that collagen implants be designed, manufactured, sold, or tested in a particular manner, so there are no federal "requirements" that could preempt petitioner's claims.

The First Circuit nonetheless held that, because respondent had obtained approval for Zyderm under the MDA's pre-market approval ("PMA") procedures, 21 U.S.C. § 360e, *see* 21 C.F.R. pt. 814, *any* claim concerning "safety or effectiveness" against the manufacturer of an approved device was preempted. In doing so, the court relied on the purported comprehensiveness of these procedures (14a, 16a), especially the need for the applicant to submit its proposed labelling with its PMA application (18a), and the importance of encouraging the marketing of devices (15a). The court failed, however, to square its ruling with the MDA's preemption provision and the FDA regulations promulgated

thereunder. In particular, none of the statutory or regulatory provisions for approval of Class III devices are device-specific in character, and, as we have noted, none require collagen implants to conform to any specifications or to be labeled in a certain fashion. The only statutes and regulations cited by the court of appeals concern *general* procedural requirements applicable to *all* Class III devices, not "specific counterpart regulations or ... specific requirements applicable to a particular device under the" MDA. 21 C.F.R. § 808.1(d).[6]

On this score, the First Circuit's decision conflicts with *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992). There, the Hawaii Supreme Court, in a case concerning defective heart pacemaker devices -- class III devices, *see, e.g.*, 21 C.F.R. §§ 870.3600-.3620 -- expressly rejected the manufacturer's argument that the PMA process preempted the plaintiff's implied warranty claim, because "the statutes and regulations governing pre-market approval set forth general procedural requirements and, therefore do not trigger preemption under [21 C.F.R.] § 808.1(b)." *Id.* at 1282.[7]

Consistent with *Larsen*, petitioner's view of MDA preemption is precisely the one taken by the FDA in regulations

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[6] As we have noted, Class III devices are those that must go through the PMA process because they are the most likely to cause patients serious harm. 21 U.S.C. § 360c(a)(1)(C). However, Class III devices that were marketed prior to the MDA's 1976 effective date or which are deemed "substantially equivalent" to pre-MDA devices need not go through the full PMA process until the FDA issues a regulation calling for the submission of PMA applications. *Id.* § 360c(f)(1)(A). The FDA does, however, require the submission of proposed labeling, among other information, to make its substantial equivalence findings, *see id.* § 360c(i)(3); 21 C.F.R. § 807.87(e), as well as clinical data in some cases similar to data filed with PMAs. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307.

[7] *Larsen* held secondarily that, since the relevant devices entered the market based on a finding of substantial equivalence, preemption was also inappropriate. 837 P.2d at 1282. Under the First Circuit's approach, which placed chief reliance on the fact that the FDA reviewed respondent's proposed labeling (18a), *Larsen*'s secondary rationale would also trigger a finding of preemption, because the applicant must submit proposed labeling in substantial equivalence cases, as well as in cases involving full PMA submissions. *See* 21 C.F.R. § 807.87(e).

defining what types of state and local authority are and are not preempted under 21 U.S.C. § 360k(a):

> State or local requirements are preempted *only where the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act*, thereby making any existing state or local requirement different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(emphasis added).

In promulgating these regulations, FDA explained why the preemptive effect of § 360k(a) must be interpreted narrowly. The Agency looked first to the words chosen by Congress, discussing the language dictating that there be a federal *requirement* with respect to *a device*, and found that device-specific federal rules must first be in place before preemption can occur. 43 Fed. Reg. 18,661, 18,662 (May 2, 1978)(highlighting italicized statutory language). The FDA further explained:

> Thus, from a plain reading of section 521 of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. ... [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling ..., which occurred when the new FDA hearing aid regulations [concerning labeling and conditions for sale] took effect.... [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution. *Id*.

This insistence upon device-specific FDA requirements for the same subject matter regulated by the state -- what the FDA refers to as the need for "specific counterpart" requirements -- is found throughout the FDA's regulations. For instance, the MDA does not preempt state or local registration or certification schemes for medical professionals simply because they "administer,

dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). If, however, the FDA exercises its authority under the MDA to restrict the use of certain devices to particular health professionals, *see* 21 U.S.C. §§ 360j(e),(g), then the federal requirements control, but only to the extent that they actually conflict with state and local regulations. 21 C.F.R. § 808.1(d)(3). And, of particular relevance here, the FDA has made absolutely clear that 21 U.S.C. § 360k(a)

> does not preempt State or local requirements of general applicability where the purpose of the requirement relates ... to other products in addition to devices (e.g., requirements such as ... *the Uniform Commercial Code (warranty of fitness)) or to unfair trade practices in which the requirements are not limited to devices* ....

21 C.F.R. § 808.1(d)(1)(emphasis added). Here, of course, petitioner's causes of action are all based on common law duties of "general applicability," and thus her implied warranty, fraud, and misrepresentations claims are specifically preserved by the FDA regulation. *See infra* Part B.[8]

2. *Conflicting Case Law.* In addition to *Larsen*, much of the case law rejects the First Circuit's approach -- that the marketing approval of a device standing alone may have preemptive effect. Rather, the cases support the FDA's view that the scope of MDA preemption is narrow and occurs only where the Agency has device-specific regulations, or where the Act itself imposes device-specific specifications in the precise area in which the state or locality is attempting to regulate.

Precedent concerning hearing aids -- a subject of early FDA regulation under the MDA -- cannot be squared with the First Circuit's approach. For example, in *Smith v. Pingree*, 651 F.2d

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[8] Petitioner's implied warranty of merchantability claim is the same type of warranty provided under the Uniform Commercial Code, Mass. Gen. Laws, ch. 106, § 2-314, and thus is expressly allowed by the FDA's regulations. Similarly, petitioner's claims for fraud and misrepresentation are directly analogous to the unfair trade practices act claims preserved in the FDA's regulation, because those acts codify and expand the common law causes of action for fraud and deceit. *See* Mass. Gen. Laws, ch. 93A, § 2.

1021 (5th Cir. Unit B 1981), the court held that a Florida law regulating the sale of hearing aids was not preempted, even though the FDA had the power to regulate in that same area and had in fact issued certain requirements with respect to hearing aids. The court held that 21 C.F.R. § 801.420(c), which requires sellers of hearing aids to provide information to prospective purchasers to promote consumer safety and improve the quality of the hearing aid, did not preempt Florida's requirement that sellers provide each purchaser with certain consumer information (*e.g.*, seller's business address, serial number of hearing aid, whether the hearing aid was new, used, or rebuilt, where consumer complaints could be filed, etc.). *Smith*, 651 F.2d at 1024-25. Contrasting the FDA's effort to protect the safety of the user with Florida's efforts to safeguard consumers' rights after purchase, the court found "that the Florida statute does not relate 'to a matter included in a federal requirement applicable to a device'" and, therefore, was not preempted by the federal regulation. *Id.* at 1025. Similarly, the court affirmed Florida's authority to require a disclaimer both on the packaging containing the hearing aid and the customer's itemized receipt concerning a hearing aid's inability to restore hearing loss, even though there existed an FDA requirement that the disclaimer appear on a brochure accompanying the hearing aid. Because the federal regulation dealt with an informational brochure, not packaging, there was no federal regulatory requirement which could be said to preempt Florida law. *Id.*

In *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978), the New Jersey Supreme Court considered numerous state regulations designed to protect hearing aid consumers, similar to, but in some ways more comprehensive than, those at issue in *Pingree*. The regulations banned the use of certain misleading professional titles, required price lists for hearing aids, barred non-consensual home visits by sellers, set price guidelines, and the like. After discussing general preemption principles, 384 A.2d at 808, the court considered the FDA's proposed regulations concerning the MDA's preemptive effect, now codified at 21 C.F.R. § 808.1. In light of the "fundamental maxim that the opinion as to the construction of a regulatory statute of the expert administrative agency charged with the enforcement of that statute is entitled to great weight," 384 A.2d at 810, the court chose to "follow the FDA's reasonable

interpretation" of § 360k(a) because there "are no 'compelling indications that it is wrong.'" *Id.* (*quoting Red Lion Broadcasting Co. v. F.C.C.*, 395 U.S. 367, 381 (1969)).[9]

Cases concerning FDA regulation of tampons are also at odds with the ruling below. For instance, in *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443 (D. Idaho 1990), the court considered a tampon manufacturer's argument that the claims of a toxic shock syndrome ("TSS") victim were preempted both by the MDA itself and by FDA regulations directing tampon manufacturers to place specific warnings on tampon packages and package inserts. *See* 21 C.F.R. § 801.430. The plaintiff claimed that her TSS was attributable to the manufacturer's breach of the duty to warn and the improper design and construction of the tampon. 750 F. Supp. at 445. The court held that the duty-to-warn claim was preempted, but that the design and construction claims were not, because federal law did not dictate a specific design or construction, only that a specific warning be given.[10]

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[9] Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984), the FDA's final regulations would be entitled to even greater respect than was accorded to the proposed regulations in *New Jersey Guild*. *See Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985)(applying *Chevron* to defer to FDA's position narrowly construing preemption).

[10] The Hawaii Supreme Court, which, as we have noted, has rejected the notion that pre-market approval for a class III device preempts state claims, *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273, 1280-82 (1992), relied heavily on *Bejarano* and other tampon cases in holding that the PMA regulations were simply too general to warrant preemption. *Id.* at 1281-82 (*citing, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 247 (5th Cir. 1989)). Indeed, the conclusion that the FDA's tampon labeling requirements preempt only state duty-to-warn claims, and leave other claims unaffected, has been followed by many courts. *E.g., Moore, supra; Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164, 169 (W.D. Mich. 1990); *Rinehart v. Int'l Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988). However, like the court below, a few courts have found broader preemption under the MDA. *See, e.g., Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993)(holding PMA preempts common law claims, despite prior ruling in *Moore*); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13 (D. Conn. 1989)(duty to warn claims for *all* prescription devices marketed after passage of MDA preempted pursuant to general labelling regulations); *Lavetter v. Int'l*

(continued...)

In sum, the court of appeals based its preemption holding on general procedural requirements for FDA device approval, rather than on any "special features warranting preemption." *Hillsborough County*, 471 U.S. at 719. That approach cannot be squared with *Larsen* and the majority of the hearing aid and tampon cases under which claims for defective design, implied warranty, and fraud were held not to be preempted despite comprehensive FDA regulation.

3. *Cipollone.* The decision below is also inconsistent with the narrow approach to preemption taken by this Court in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). There, the Court considered the preemptive effect of § 5(b) of the Public Health Cigarette Smoking Act of 1969, on a variety of damage claims raised by a cigarette smoker who had died from using the defendant's product. Section 5(b) provided that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 2617. Section 4 of the Act mandated that a specific warning be placed on all cigarette packaging and advertising. *Id.* at 2616.

The four-Justice *Cipollone* plurality rejected the manufacturer's argument that all of the plaintiff's damage claims were preempted, and instead analyzed each cause of action in light of § 5(b)'s language and purposes. Because Cipollone's duty-to-warn claims would create state-imposed tort liability on the basis of a failure to give a warning over and above *the specific warnings required by Congress*, those claims were preempted. *Id.* at 2621.

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[10](...continued)
Playtex, Inc., 706 F. Supp. 722, 723 (D. Ariz. 1988)(preempting entire claim, but unclear whether plaintiff made claims other than duty to warn); *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982)(preempting state law claim for warning to users of Dalkon Shield on ground that federal interest in medical devices is "dominant" and "pervasive," without citation or analysis of statutory or regulatory provisions on preemption). We note that the FDA rejected the broad preemption holding in *National Women's Health* in an advisory opinion holding that the MDA was not intended to preempt common law remedies at all (*see* 25a-26a, discussed *infra* 22).

But other claims -- fraudulent misrepresentation, conspiracy to misrepresent or conceal facts, and breach of warranty -- were not preempted because, while they dealt with "smoking and health" in some sense, they were grounded legally on either a general tort duty not to deceive or on a contractual relationship between the parties. *Id.* at 2623-24 & n.27.

Under *Cipollone*, then, the duty-to-warn claims were preempted precisely because mandatory federal warnings were the centerpiece of a federal law and of its preemption provision; in the tampon cases (discussed *supra* at 17 & n.10), such claims were held preempted for the essentially same reason -- that mandatory warnings were the subject of a specific federal requirement. But also for the same reason, the tampon cases, consistent with *Cipollone*, generally hold that design defect claims are not preempted, because tampon design is not the subject of a federal requirement. Put another way, if the FDA had promulgated mandatory labeling for all collagen implants, as it has for tampons and hearing aids, then *Cipollone* might arguably require preemption of petitioner's failure-to-warn claims, but no others.[11]

Cipollone's holding that fraud-based claims were not preempted is particularly noteworthy, because the general tort duty not to deceive, to which the Court referred in *Cipollone*, is the same duty upon which petitioner relies in her fraud and misrepresentation counts. The First Circuit's response -- that because the only fraud alleged by petitioner was perpetrated on the FDA in approving and labeling the device, it was up to the FDA, not the tort system, to redress the problem -- is faulty for two reasons. First, a jury award based on fraud on the FDA does not, under § 360k(a), establish a "requirement" with respect to Zyderm "different from, or in addition to" a pre-existing MDA requirement on that subject matter. Rather, as in *Cipollone*, the cause of action is based on a general duty not to deceive, and has no basis in any particular MDA requirement. Second, petitioner's claims extend beyond fraud on the FDA, to the alleged deception

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[11] However, as we explain in Part B *infra*, damage actions are wholly outside the MDA's preemption provision because that provision differs materially from the one at issue in *Cipollone* and the FDA has reasonably construed the MDA to preempt only positive enactments of state and local governments.

of petitioner and her doctor (21a n.8), which obviously has nothing to do with the PMA approval process. Furthermore, as the court of appeals noted (19a), the preemption of the fraud claims is in direct conflict with the Fifth Circuit's decision in *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1180 (1988), which held that a fraud cause of action was not preempted by FDA's approval of a vaccine's labeling.[12]

Given the incompatibility of the court of appeals' decision with other lower court decisions as well as with *Cipollone*, this Court should grant review.

B. Review Should Be Granted Because, Contrary to the Holding Below, The MDA, as Authoritatively Construed by the FDA, Does Not Preempt Any Common Law Damage Claims.

The First Circuit's decision also warrants this Court's consideration because, in finding that all of petitioner's claims were preempted, the court necessarily held that Congress intended to preempt common law damage claims. In doing so, the court of appeals rejected petitioner's contention that Congress intended to limit the preemptive scope of § 360k to the positive enactments of state and local governments. While the courts have expressed differing views on the preemptive scope of § 360k -- generally finding preemption of at least some types of damage claims -- the preemption of state-law damage claims ascribes to Congress an intent that cannot be squared with the statutory language, the legislative history, or the FDA's regulations.

In *Cipollone*, this Court held that, under the Smoking Act of 1969, a "requirement ... based on smoking and health ... imposed under state law" was a reference to a common law damage claim, as well as positive statutory and regulatory law. 112 S. Ct. at 2620-21. It did so on the basis of various statutory indicia, including legislative history and a change made from a prior version of the Act, all of which pointed in the direction of preemption of some damage claims. *Id.*

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[12] We note that this circuit conflict is not vitiated by the Fifth Circuit's ruling in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (1993), which generally followed the decision below, because *Stamps* expressly did not reach the fraud claims. *Id.* at 1422 n.5.

Thus, while "a requirement ... *under state law*" may, in some circumstances, include common law claims, review of the specific provision at issue here -- 21 U.S.C. § 360k -- demonstrates that damage claims are not preempted under the MDA. Section 360k(a) does *not* refer generally to all "state law," language that was critical to the analysis in *Cipollone*; it says that "no State or political subdivision of a State may establish or continue in effect with respect to a device" certain requirements. In some situations, a "requirement" under § 360k(a) may encompass a judicial order (such as the enforcement or the interpretation of a state law or regulation concerning devices), *see* 21 C.F.R. § 808.1(b); however, it strains ordinary English usage well past the breaking point to say that a jury award to a tort plaintiff such as petitioner constitutes a "State or political subdivision of a State establish[ing] or continu[ing] in effect" a device requirement, especially when measured against the strong presumption against preemption that animates this Court's jurisprudence. *See Mortier*, 111 S. Ct. at 2482, 2485.

Read most naturally, § 360k(a) concerns state and local statutes, ordinances, and regulations that impose affirmative requirements on device manufacturers, such as those at issue in *New Jersey Guild, supra*. Not surprisingly, neither the legislative history, H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 4, 45-46 (1976), nor the extensive regulatory history, concerning both the scope of FDA preemption in general and the Agency's regulatory decisions on whether specific state requirements are preempted, even suggest, let alone make explicit, that common law remedies are preempted. Rather, the legislative history and the FDA's regulatory comments are replete with references to the preemption provision's application to the actions of state and local legislative and regulatory bodies.[13]

Indeed, as we noted earlier (*supra* at 14-15), shortly after passage of the MDA, the FDA issued regulations making clear that tort-like remedies are not preempted. "State or local requirements

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[13] H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 4, 45-46 (1976); 45 Fed. Reg. 67,321-67,324 (Oct. 10, 1980); 43 Fed. Reg. 18,662-18,664 (May 2, 1978); *see also Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989)(relying on legislative history).

of general applicability" that "relate[] to other products in addition to devices ... or to unfair trade practices in which the requirements are not limited to devices" are not preempted. 21 C.F.R. § 808.1(d)(1). Thus, damage claims based on common law duties would not be preempted because they "generally pertain ... to persons who manufacture or distribute devices ... ," and other tortfeasors, "and [do] not [pertain] directly to devices." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978).[14] "In order for a State provision to be a requirement with respect to a device within the meaning of section 521 of the act -- and thereby a candidate for preemption -- it must relate to the device itself." *Id.* This is precisely why the FDA, in an advisory opinion, rejected the preemption holding in *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982), where the plaintiff had sought a warning to all users of the Dalkon Shield intrauterine device *under Massachusetts tort law*. The FDA stated that "the act preempts only State and local requirements that directly and specifically relate to devices" (26a). Thus, "*[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to a device' within the meaning of section 521(a) of the act*" (*id.*)(emphasis added).[15]

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[14] That is why, contrary to the decision below, the only state or local regulations preempted by PMA requirements for a specific device are state-based PMA procedures themselves. *See, e.g.*, 45 Fed. Reg. at 67,323 (states may require pre-market approval of a specific device, even after passage of MDA, until FDA requires such approval for that device).

[15] This advisory opinion (25a-26a) was issued by the FDA's Associate Commissioner for Regulatory Affairs pursuant to delegated authority, *see* 21 C.F.R. § 808.5, and represents at least as strong a barometer of FDA policy as did the regulatory commentary deferred to by this Court in *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985)(deferring to FDA's position narrowly construing preemption of state and local regulation of blood donation centers, despite comprehensive federal regulation). Moreover, the FDA advisory opinion was reiterated by the Chief of FDA's Regulations Staff in a February 1987 letter, which stated that 21 U.S.C. § 360k(a) "preempts only state and local requirements that are specifically related to medical devices. Therefore, *FDA believes that section 521 [§ 360k(a)] does not preempt general product liability requirements*" (27a)(emphasis added).

Moreover, the existence of 21 U.S.C. § 360k(*b*) -- a provision mentioned only in passing by Judge Tourrella (7a), and not at all by Judges Aldrich and Campbell -- further undermines the contention that § 360k(a) is applicable to common law claims. Subsection (b) allows States or their political subdivisions to apply to the FDA for exemptions, so that they can maintain requirements that are otherwise preempted. Subsection (b)'s language is parallel to that of subsection (a), *i.e.*, it permits exemption of any requirement that may be preempted under subsection (a), and thus allows applications only from "States or political subdivisions" to exempt "requirements" "applicable to a device for human use." 21 U.S.C. § 360k(b).

The legislative history of subsection (b) also makes clear that exemptions may be sought for anything preempted under subsection (a), and refers solely to the exemption of "regulation[s]" and other positive enactments issued pursuant to state law. H.R. Rep. No. 94-583, *supra* at 45. Therefore, the FDA's exemption regulations construing subsection (b) begin by stating that a "State or political subdivision may apply ... for an exemption from any requirement it has *enacted* ... ." 21 C.F.R. § 808.20(a)(emphasis added); *see also id.* § 808.20(c)(1)(requiring jurisdiction seeking exemption to submit "any statute, rule, regulation or ordinance" for which exemption is sought). Thus, subsection (b) does *not* apply to the establishment of common law duties or jury awards. To suggest that subsection (a), however, does apply to damage awards makes no sense and would impose upon § 360k an awkward and illogical asymmetry that is flatly contradicted by the statute and the FDA's regulations.

We recognize that most courts, *see Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1062 n.2 (D. Minn. 1989)(collecting cases), have held that subsection (a) can preempt some common law claims, but almost all of them -- like the court of appeals here -- have simply assumed that conclusion, and *none* of the courts finding preemption has even considered the effect of subsection (b). The one court to have considered subsection (b) in a damage action held that "[t]he plain language of § 360k indicates that Congress intended to preempt state or local legislation and administrative regulations governing devices, not state tort law." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989)(alternative holding). The court explained that, "if the term

'requirement' were interpreted so as to include tort law, the exemption provision [of 21 U.S.C. § 360k(b)] would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of an IUD tort plaintiff?"[16]

In petitioner's view, the MDA plainly does not contain the "clear and manifest" Congressional purpose necessary to preempt any common law tort liability. *See Mortier*, 111 S. Ct. at 2482, 2485; *Cipollone*, 112 S. Ct. at 2626 & n.1 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). In any event, the First Circuit's decision that 21 U.S.C. § 360k(a) expressly ousts state law-based jury awards is sufficiently problematic to warrant review, especially given its evident incompatibility with the views of the FDA.[17]

C. Review Should Be Granted Because of the Manifest Importance of the Court of Appeals' Ruling.

As we noted at the outset, the former Chief Counsel of the FDA views the decision below as probably the most important medical-device case in history. This is not surprising because, even if viewed as applying only to Class III devices currently subject to pre-market approval, the court of appeals' decision would preempt all claims against the manufacturers of millions of potentially deadly devices, such as heart valves, 21 C.F.R. § 870.3925, breast implants, *id.* § 878.3540, intraocular lenses, *id.* § 886.3600, various implantable devices for the treatment of epilepsy and other neurological disorders, *id.* §§ 882.5820-.5840,

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[16] *Accord Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298 (D. Minn. 1989)(dicta); *cf. New Jersey Guild*, 384 A.2d at 813-14 (existence of § 360k(b) is strong evidence of narrow preemptive scope of § 360k(a)). In addition, at least two district courts have held in unreported decisions that § 360k(a) does *not* preempt any common law claims. *Discussed in Berger v. Personal Products, Inc.*, 797 P.2d 1148, 1151 & n.16 (Wash. 1990).

[17] Given the tension between the FDA's pronouncements and the rulings of some courts, including the court below, this Court may want to invite the Solicitor General to express the Agency's views, as it did in *Kievlan v. Dahlberg Electronics, Inc.*, 78 Cal. App. 3d 951 (1978), *appeal dismissed*. 440 U.S. 951 (1979), an early MDA preemption case. *See also* 18a (FDA's interpretation of the statute must give way to court of appeals' understanding of MDA).

and hundreds of other devices intended to improve or sustain human life. The decision below displaces virtually all state-law remedies against the manufacturers of such devices, regardless of the extent of the patient's injuries or the manufacturing or design defects, even if FDA approval was procured through the manufacturer's fraud.

In petitioner's view, the court of appeals paid too little attention to the statute and regulations and instead employed a cost/benefit analysis, deciding that the MDA favored the marketing of new devices at the expense of "a few individuals [who] may be denied full protection ... " (15a). This perspective is best illustrated by the court's charge that petitioner is among the "idiosyncratic individuals" (19a) for whom a remedy must give way to the exigencies of the marketplace. However, poor device design and manufacturing practices, and fraud in the procurement of FDA Class III approval, has been blamed for the deaths of hundreds of heart valve recipients, who, because the device went through the PMA process, presumably would be without a remedy under the First Circuit's approach.[18] Similarly, there would be no remedy for patients injected with an opthalmic gel used to facilitate implantation of intraocular lenses that proved to be unduly dangerous, despite having received FDA approval.[19] Indeed, in this case, although there is no specific evidence of widespread illness, Zyderm's true toll is unknown, given respondent's alleged underreporting of adverse incidents (A00479), which, among other things, led to a Congressional investigation (A00523-A00525).[20]

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[18] *See generally* Staff Report of the Oversight and Investigating Subcommittee of the Committee on Energy and Commerce of the U.S. House of Representatives, *The Bjork-Shiley Heart Valve: "Earn As You Learn"* (GPO Feb. 26, 1990).

[19] *See* Oversight and Investigating Subcommittee of the Committee on Energy and Commerce of the U.S. House of Representatives, *Less Than the Sum of its Parts -- Reforms Needed in the Organization, Management, and Resources of the FDA's Center for Devices and Radiological Health* 31-33 (GPO May 12, 1993).

[20] *See generally id.* (describing serious problems with various devices, including Zyderm (at 23-24)); *see also supra* note 3.

At bottom, the court of appeals' economic analysis may or may not be correct, but it has nothing to do with whether Congress expressly intended to preempt state-law damage claims for Class III devices and has no basis in this Court's Supremacy Clause jurisprudence, which has been loathe to preempt state damage claims, where, as here, "Congress [has] fail[ed] to provide any federal remedy for persons injured by" respondent. *Silkwood*, 464 U.S. at 251. As the foregoing discussion indicates, "Congress would [not], without comment, remove all means of judicial recourse for those injured by [the] illegal conduct" of device manufacturers, as the FDA itself has recognized in its regulations and other authoritative pronouncements. *Id.*; *accord English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Callan*, 709 F. Supp. at 667.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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June 13, 1993

In the United States Court of Appeals
for the First Circuit

No. 92-1278

JANE KING
Plaintiff, Appellant

v.

COLLAGEN CORPORATION,
Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
[Hon. A. David Mazzone, U.S. District Judge]

Before
Torruella, Circuit Judge,
Aldrich and Campbell, Senior Circuit Judges.

Clinard J. Hanby, with whom Susan A. Allinger, John O' Quinn, O'Quinn, Kerensky & McAninch, Michael M. Essmyer, Michael M. Essmyer & Associates, Frank Lynch and LeComte, Emanuelson, Tick & Doyle, were on brief for appellant.

Bob Gibbins and Jeffrey R. White, were on brief for the Association of Trial Lawyers of America, amicus curaie.

Joseph J. Leghorn, with whom Peter T. Wechsler, Warner & Stackpole, Joe W. Redden, Jr., W. Curtis Webb, and Beck, Redden & Secrest, were on brief for appellee.

Bruce N. Kuhlik, Lars Noah, Covington and Burling, Edwin H. Allen, and Retta M. Riordan, were on brief for Health Industry Manufacturers Association, amicus curaie.

January 15, 1993

TORRUELLA, Circuit Judge. Jane King appeals from a grant of summary judgment entered in favor of Collagen Corporation ("Collagen") by the United States District Court for the District of Massachusetts. The district court determined that plaintiff's claims were preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq. Because the district court correctly construed the preemption provision of the MDA, we affirm.

FACTS

Defendant Collagen manufactures and distributes Zyderm, a cosmetic medical device used to correct wrinkles and other skin deformities. Zyderm treatment consists of injecting processed cow tissue directly under the skin. Zyderm then supports the skin from underneath, smoothing out deformities on the surface of the skin. The course of treatment may run for several weeks and requires up to six applications. Researchers at Stanford University developed Zyderm in the early 1970's and Collagen placed it on the market in the early 1980's.

As a medical device, Zyderm falls within the scope of the MDA and thus must be approved and regulated by the Food and Drug Administration ("FDA"). As a Class III medical device under the MDA scheme, it is subject to the most extensive pre-marketing approval requirements imposed by the MDA and to similarly extensive regulation post-approval. The premarket approval process is designed to provide a "reasonable assurance of ...safety and effectiveness" for medical devices which are too dangerous or unknown to permit less regulation. 21 U.S.C. § 360(1)(c). Post-approval regulation is designed to keep the FDA apprised of ongoing safety findings or any other information about the device as it becomes available. Id. §§ 360e(e) & 360i(a).

Pursuant to the pre-marketing approval process, the FDA requires applicants to submit proposed labeling, extensive safety testing data and descriptions of manufacturing methods and materials. Id. § 360e(c)(1). Upon reviewing the materials in a comprehensive manner, the FDA may approve the device for sale or return the application to the applicant for further information or testing. Id. § 360e(d)(1). When the FDA returns an application to the applicant, the FDA must apprise the applicant of how to

correct all deficiencies. Id. § 360e(d)(2). Once the device is approved, the FDA retains the power to withdraw approval of the product permanently or suspend its approval temporarily if it determines that the device has become unsafe or its labeling inadequate. Id. § 360e(e)(1)(3). To assist the FDA in making these determinations, manufacturers must maintain records and make reports to the FDA on information pertinent to the device. Id. § 360i(a). Zyderm passed through the Class III approval process prior to marketing, and underwent revisions to the original approval afterwards.

Appellant Jane King sought Zyderm treatment in 1987. Following the normal procedure, Ms. King's physician administered a test dose of Zyderm before proceeding with the full treatment. Shortly after receiving this test dose, Ms. King suffered muscle and joint pains as well as other symptoms. Her doctor subsequently diagnosed her as having dermatomyositis/polymyositis ("DM/PM"), an autoimmune disease in which the immune system attacks skin and muscle tissue as if it were a foreign substance.

When Ms. King received Zyderm, Zyderm's FDA-approved labeling contraindicated use by those with a personal history of autoimmune disease. Since that time, however, the FDA has gradually allowed Collagen to change the labeling as it related to autoimmune disease. By 1991, Zyderm was no longer contraindicated for persons with a history of autoimmune disease. The FDA required a warning in 1991, however, that some recipients have suffered from unwanted autoimmune reactions, but that no causal connection between Zyderm and these reactions has been shown.

Ms. King subsequently filed a first amended complaint detailing seven claims against Collagen.[1] First, she claimed that

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[1] Ms. King filed suit against Collagen in 1990 alleging that the test dose of Zyderm caused her to develop DM/PM. Count one of her suit alleged that Collagen negligently tested, manufactured and sold Zyderm. Count two alleged that Collagen breached implied warranties of merchantability. Count three alleged fraud and deceit in the sale of Zyderm.

Ms. King subsequently filed the amended complaint. Appellee contends that Ms. King informed appellee that she would withdraw this amended complaint.

Collagen was strictly liable for her injuries because Zyderm was unsafe for its intended purpose and unreasonably dangerous to users. Second, she alleged that Zyderm was not safe and fit for the purpose intended and therefore sold in breach of the warranty of merchantability. Third, Ms. King alleged that negligence in the design, manufacture, marketing and sale of Zyderm, including negligence in not revealing dangerous propensities of the product, led to her injury. Fourth, she maintained that Collagen misbranded and/or mislabeled Zyderm. Fifth, she asserted that Collagen made misrepresentations of material fact to Ms. King in selling Zyderm to her. Sixth, she alleged that Collagen failed to warn her of any defective condition. Finally, Ms. King alleged that Collagen fraudulently obtained FDA approval.

Collagen moved for summary judgment shortly after Ms. King filed her amended complaint, arguing that FDA regulation of Zyderm under the MDA preempted all of the causes of action alleged in the complaint. The district court granted this motion, relying on a similar case from the Southern District of Texas. This case, Stamps v. Collagen Corp., No. H-90-2242, 1991 U.S. Dist. LEXIS 20666 (S.D. Tex. 1991), held that Plaintiff's various products liability claims arising out of Zyderm treatment were preempted by FDA regulation under the MDA.

LEGAL ANALYSIS

I.

Article VI of the Constitution dictates that federal law "shall be the supreme Law of the Land; and the judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State notwithstanding." U.S. Const. art. VI, cl. 2. State laws that conflict with federal laws and regulations, therefore, are preempted. E.g., Malone v. White Motor Corp., 435 U.S. 497

As such, appellee never opposed its entry. The district court entered the amended complaint, noting that no opposition was filed. The district court, however, proceeded to grant summary judgment on the basis of Ms. King's original complaint. Because the amended complaint contains essentially similar claims as the original complaint, with few additions, we will address the claims in the amended complaint.

(1978). In determining whether such a conflict exists, it is well settled that the intent of Congress governs. That is, preemption does not occur unless Congress so intended. Rice v. Santa Fe Elevator Corp., 435 U.S. 497, 504 (1978).

Congress may express its intent to preempt state law explicitly in the language of the statute. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). Congress may express its intent implicitly by passing an extensive statutory scheme that extensively covers the field of regulation. Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982). Implied preemption also occurs when a conflict between state and federal law makes compliance with both impossible, or when state law would frustrate the purpose and objectives of the federal law. Id. (citing Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963); Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

We are aided in our determination of preemption in this case by the Supreme Court's recent treatment of the subject in Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992). In Cipollone, a victim of lung cancer sued several cigarette manufacturers for breach of warranties contained in cigarette advertisements, for failure to warn of health hazards related to smoking, for fraudulently misrepresenting those hazards to the public, and for conspiracy to deprive the public of important health information. Id. at 2613. The cigarette manufacturers contended that petitioner's claims were preempted by the federal law requiring a health warning to appear on all cigarette advertisements and containers.[2] Id. at 2614.

In analyzing preemption, the Court relied only on the specific language of the provision regarding preemption. The Court reasoned that "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted." Id. at 2618. The opinion thus analyzed

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[2] That law stated that "[n]o requirement or prohibition based on smoking or health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the Provisions of this Act." Federal Cigarette Labeling and Advertising Act of 1965, § 5, as amended by Public Health Cigarette Smoking Act of 1969, § 2, 15 U.S.C. § 1334.

each of petitioner's claims in light of the express language of the preemption provision in the cigarette warning statute.

The plurality held that the provision preempted failure to warn claims as to advertising practices, but not as to testing or research practices. Id. at 2621-22. The plurality reasoned that the Act only preempted state law claims arising out of cigarette advertising and promotion, and that appellant's claims arising out of testing and research did not relate to advertisement and promotion. The provision preempted petitioner's fraudulent misrepresentation claim that cigarette advertising neutralized the effect of the warning in a similar fashion. Id. at 2623-24. The provision, however, did not preempt fraud claims arising out of communication other than advertising, such as information required to be disclosed to an administrative agency, or out of fraudulent statements made in the advertising but unrelated to the health warning. Id.

The plurality further held that the provision did not preempt express warranty claims, because those claims arose due to the conduct of the manufacturers who made the warranties rather than from state law. Id. at 2622. Finally, the plurality held that the provision did not preempt the conspiracy to deprive the public of material facts claims, because they did not arise out of state law pertaining to smoking and health, but rather arose out of a "duty not to conspire to commit fraud." Id. at 2624.

The analysis of the plurality in Cipollone guides our analysis in this case. We begin by noting that the express preemption provision in the MDA, 21 U.S.C. § 360k, forecloses inquiry into implied preemption, because the fact that Congress included it in the MDA implies that matters beyond its reach are not preempted. Further, we note that the Cipollone plurality carefully construed the preemption provision to extend no further than its language warranted. In doing so, the plurality sought to pay proper respect to federal-state relations. This concern arises out of "the assumption that the historic police powers of the states [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." Cipollone, 112 S. Ct. at 2617 (citing Rice, 331 U.S. at 230). We too will carefully construe the preemption provision of the MDA to give due regard to questions of federal-state relations.

II.

Bearing these principles in mind, we turn to the language of the statute in question. The MDA states that

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. Under subsection (b) of § 360k, a state may petition the FDA in certain circumstances to allow state requirements to continue in force. Because no such petition affects this case, we are concerned only with the preemptive effect of subsection (a). Under subsection (a), we must determine whether appellant's products liability claims give rise to state law requirements in addition to or different from those mandated by the FDA.

We turn first to the FDA's own understanding of subsection (a) for guidance. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) (agency's interpretation of its own statute is controlling so long as not contrary to Congress' intent). FDA regulations provide that preemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device. 21 C.F.R. § 808.1(d). In this case, it is clear that the requirements on Zyderm related to labeling, design, manufacturing and other aspects of the device pursuant to the MDA scheme.

If the FDA has issued requirements for a device, subsection (a) prohibits states from imposing any requirements which differ from or add to the FDA requirements, or which relate to the safety or effectiveness of the device. A "State . . . requirement" in subsection (a) may emanate from any requirement established by

a state including statutes, regulations, court decisions or ordinances. 21 C.F.R. § 808.1(b); see also San Diego Building Trades Council v. Garmon, 359 U.S. 236, 247 (1959) ("[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing-conduct and controlling policy.").

The language of subsection (a) and the definition of state requirement promulgated under it demonstrate a field of preemption which is broad, but limited. Any state requirement which, in effect, establishes a new substantive requirement for the device in a regulated area such as labeling, is preempted. 21 C.F.R. § 808.1(d)(6)(ii). As the Seventh Circuit noted, however, subsection (a) of the MDA does not preempt such claims as negligent implantation or removal of devices, or claims arising out of contaminated devices. Slater v. Optical Radiation Corp., 951 F.2d 1330, 1334 (7th Cir. 1992), cert. denied, 1992 U.S. LEXIS 6436 (Oct. 13, 1992).

Armed with this understanding of subsection (a), we will analyze petitioner's claims individually to determine the effect of the MDA preemption provision on each.

A. Strict Liability

Appellant contends that Zyderm is unsafe for its intended purpose and unreasonably dangerous to users, and that Collagen therefore is liable for any injuries Zyderm may cause. Indeed, class III devices such as Zyderm are those that present a "potential unreasonable risk of illness or injury" such that extensive regulation is required to ensure reasonably safe use. 21 U.S.C. § 360c(a)(1)(C). The FDA must evaluate these devices with regard to those for whose use the device is intended. Id. § 360c(a)(2)(A). The entire MDA scheme for such Class III devices as Zyderm, therefore, is aimed at determining and regulating the intended purpose of the device, and at ensuring a reasonable level of safety for its users.

It is clear that appellant's strict liability claim would impose requirements related to the safety and effectiveness of Zyderm. If successful, the claim would require Collagen to redesign Zyderm, remove it from the market, or be subject to strict liability. The

MDA does not permit this. Appellant's claim would force us to determine that Zyderm is unsafe and dangerous, in opposition to the contrary determination made by the FDA under the MDA. Subsection (a) protects manufacturers of medical devices approved by the FDA under the MDA from such state law intrusion.

B. Breach Of Warranty

Appellant claims that Collagen breached express and implied warranties of merchantability and fitness for a particular purpose. Appellant's express warranty claims arise out of the labeling and packaging of Zyderm, all of which are regulated by the FDA. In labeling and packaging, Collagen could not say any less than what the FDA required, and appellee could openly add extra warnings or safety information, but not warranties, without FDA approval. Appellant's express warranty claims therefore are preempted because any such warranties only could arise out of the FDA-approved labeling and packaging. Allowing appellant's express warranty claims effectively would impose additional or different requirements on Zyderm's labeling and packaging.

We note that the Court's holding in Cipollone would seem to require the opposite result in this case. However, the warnings at issue in Cipollone were different than those here. In Cipollone, the statute required cigarette manufacturers to include a brief health warning in their advertisements; this warning did not affect cigarette advertisements in any other way. The manufacturers were free to make any claims they wished, including express warranties. Here, however, the MDA has imposed much more extensive regulation upon class III device manufacturers. The FDA retains rigid control over the entirety of the labeling and packaging of class III products, largely displacing the ability of manufacturers to make additional claims. This high level of control contrasts with the low level of control in Cipollone, and ensures that manufacturers will not be held liable for packaging and labeling imposed by the FDA.

Appellant also alleges that Collagen breached an implied warranty of merchantability, and that this breach caused her injuries. As an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, this

claim is preempted expressly by the MDA. Otherwise, it would impose a requirement additional to those imposed under the MDA.

C. Negligence

Appellant's third claim alleges negligence in the design, manufacture, marketing and sale of Zyderm. This claim also is preempted by the MDA. If the MDA does nothing else, it regulates the design, manufacture, sale and marketing of class III medical devices in an extensive way. The MDA does this through the packaging and labeling requirements which directly affect the marketing and sale of the product. The same requirements also affect the design and manufacture of the product in that these processes must be approved by the FDA and described in the product's packaging and labeling.

As the design, manufacture, marketing and sale of Zyderm is the subject of FDA regulation, the negligence claim is preempted. Otherwise, a finding of negligence would force Collagen to alter these aspects of Zyderm in response to the finding of liability, or be subject to liability. Either result impermissibly would impose an additional or different state requirement upon the design, manufacture, marketing and sale of Zyderm.

D. Product Misbranding, Misrepresentation & Failure to Warn

Appellant contends that Zyderm was misbranded or mislabeled. Misbranding generally occurs when labeling is "false or misleading" in any particular. 31 U.S.C. § 352(a). Under the MDA, the FDA must reject proposed labeling when the labeling is "false or misleading in any particular." Id. § 360e(d)(2)(D). As there is no indication in the record that the Zyderm administered to Ms. King was anything but what the FDA-approved labeling said it would be, notwithstanding appellant's bald statements, we find this claim preempted.

Appellant's fifth and sixth claims of misrepresentation and failure to warn are preempted for similar reasons. A finding that Collagen misrepresented Zyderm to appellant would impose a requirement on Collagen to change its packaging or labeling in order to correct the misrepresentation. The failure to warn claims

similarly challenge the adequacy of Zyderm's FDA-regulated packaging and labeling. The MDA forecloses these claims because Collagen cannot be forced to change Zyderm's packaging and labeling by virtue of these state law damage claims.

E. Fraud

Appellant's final cause of action alleges that Collagen fraudulently obtained FDA approval at the premarketing stage of the MDA process, and asks for treble damages due to the fraud. This cause of action is more unclear than her other causes of action. Collagen insists that the claim originally was based upon Mass. Gen. L. ch. 231, § 85J, an antifraud statute, while appellant urges that it was based on a more general duty not to deceive.

Section 85J provides that "[w]hoever, by deceit or fraud, sells personal property shall be liable in tort to a purchaser in treble the amount of damages sustained by him." The language of this statute corresponds to Ms. King's fraud claim in providing for treble damages. Because Ms. King has not specified any applicable statute, or other reason why she is entitled to treble damages under a general duty not to deceive, we must conclude that the fraud claim originally arose under § 85J. The district court made the same finding in its memorandum and order in this case.

To state a claim for fraud under § 85J, the plaintiff must be in privity with the seller. Kourouvacilis v. General Motors Corp., 410 Mass. 706, 575 N.E.2d 734, 735 (1991). In this case, no privity existed between appellant and Collagen, as Collagen only sold its product directly to appellant's physician. Thus, as a matter of Massachusetts law, appellant's fraud claim must fail.

We further note that the fraud claim is, at bottom, a failure to warn claim. It seeks to show that Collagen had a duty to provide different information in Zyderm's packaging and labeling than that which was approved by the FDA. As such, the claim is preempted expressly by the MDA.

CONCLUSION

Because we have determined that the MDA expressly preempts Ms. King's state law tort claims, the judgment of the district court is affirmed.

"Concurrence follows"

ALDRICH, Senior Circuit Judge, with whom CAMPBELL, Senior Circuit Judge, joins, concurring. While we agree with our brother Torruella's result, and a good deal that he says, we approach this case somewhat differently. First, a matter of housekeeping. On December 13, 1991, a year past the scheduled date for completion of the pleadings, plaintiff filed a motion to allow an amended complaint, accompanied by the complaint. On December 17 she wrote defendant that she would withdraw her motion. Defendant, accordingly, did not oppose. On December 27 defendant moved for summary judgment. In opposing defendant's motion for judgment plaintiff made no mention of the proposed new complaint, but, in fact, she did not withdraw her motion, and the court later allowed it. However, the court's ultimate order granting summary judgment did not mention the amendment.

At first blush we might agree with defendant's objection that there were substantive additions in the amended complaint, particularly with relation to fraud. Apart from fraud, the rest of the amended complaint contains six claims as against, originally, two -- negligence and breach of implied warranty. There was definitely a purported enlargement -- a state tort of strict liability, and a claim of express warranty. While the negligence alleged is limited to designing and producing a dangerous product, and not that the sample sold plaintiff was in some way a departure and individually defective, plaintiff adds mislabeling and misrepresentation, and, finally, failure to warn.

Taking defendant's now alleged seven sins, we group them as follows. Strict liability (negligent design), implied warranty, negligence, mislabeling, and failure to warn are really all of a piece -- failure to warn. On the record it is clear that had there been a warning that the product might cause the disease that plaintiff allegedly suffered she would have no claim under any of these headings. On this basis there is thus no real enlargement by the amended complaint. Express warranty might be enlargement,

but there is no basis for claiming it.[3] Finally, fraud and misrepresentation are not as newly put as they look. Defendant would have it that the original allegation related only to representations made to the plaintiff. Plaintiff states that she intended her language to include misrepresentations to the agency. Two of her exhibits seeking to raise an issue on the motion for summary judgment bear this out. The amendment should stand, as mere clarification. However, we read fraud more broadly than does our brother, and shall return to it later.

All agree that there is one basic issue: federal preemption. Preemption may apply against state judicial as well as legislative action,[4] Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992), and may take two forms, express and implied, with a heavy burden upon the party asserting it. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). This is especially so when the subject is the state interest in health and safety. Hillsborough County v. Automated Medical Labs, Inc., 471 U.S. 707, 715, 718-19 (1985). The question is Congressional intent. Wood v. General Motors Corp., 865 F.2d 395, 401 (1st Cir. 1988), cert. denied, 494 U.S. 1065 (1990). Here, concededly, the statute's purpose is health protection, but the parties disagree as to its scope. Plaintiff says it is directed to the individual user by keeping harmful products off the market and assuring proper warnings. Defendant says it is also to benefit the public at large by shielding regulated manufacturers against inconsistent state regulation, including lawsuits. If their legal risks may be too great, worthwhile medical devices may be left in the laboratory, to the public's loss.

Public health is a valid federal purpose, and Congress can reasonably weigh possible loss to the idiosyncratic few against

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[3] Express warranty might have created a problem for the defense of preemption, cf. Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608, 2622-23 (1992).

[4] A matter that may have troubled the court in Wood v. General Motors, post. See, also, 21 C.F.R. 808.1(b).

benefits to the public generally. See, e.g., Mary Beth Neraas, The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis? 63 Wash. L. Rev. 149 (1988). The legislative history shows that this was precisely the Congressional intent. Concededly, the U.S. Code Congressional and Administrative News, 94th Congress, Second Session, Vol. 3, pp. 1070 et seq., Medical Device Amendments of 1976, shows the principal emphasis to be on the protection of the individual user. But it also shows the intent to "encourage. . . research and development" and "permit new and improved devices to be marketed without delay." Infra. Perfection is impossible and a few individuals may be denied full protection at the cost of benefitting the rest.

Contained within the Senate Report (94-33)[5] are the following.

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development. [1071]
>
> S. 2368 recognizes the benefits that medical research and experimentation to develop devices offers to mankind. It recognizes, too, the need for regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices. [1075]
>
> The Committee recognizes the rapidly changing nature of the devices field and therefore feels that provisions must be made to amend standards on the basis of improved technology or new scientific evidence. Such amendments should

> be made in an expedited fashion so that appropriate changes can be rapidly implemented. The purpose of this authority is to permit new or improved devices to be marketed without delay so that the public may have such beneficial devices available to them as soon as possible. [1083]

Translating to a simple concept, and taking the difference of opinion between the parties to be whether the FDA requirements are merely minimum, or are the total maximum protection afforded the individual user, we believe this a clear demonstration of Congressional choice of the latter. We further find that the comprehensive statutory language conforms thereto.

21 U.S.C. § 360e(c)(1) provides,

> (1) any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain --
>
> > (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
> >
> > (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
> >
> > (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

Following these detailed requirements, and we note especially subsection (F), comes Section 360k(a).

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety of the device or to any other matter included in a requirement applicable to the device under this chapter.

Particularly in the light of the legislative history we read this as maximum protection and express preemption, leaving no need to seek implications. As all but one of plaintiff's sustainable claims are premised on a failure to warn, preemption here is unavoidable, given the subsection (F) requirement that labels be reviewed by the FDA.

It followed that most of plaintiff's arguments are beside the mark. A few, however, may deserve mention. Plaintiff claims that because of the regulation reported in 21 C.F.R. 814.39(d)(1), to the effect that a manufacturer "may," without prior approval, make certain changes that enhance safety, defendant had a duty to make such here. It is sufficient to say that to interpret "may" as "should" would unravel the entire garment. Second, citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984), plaintiff says that, if defendant is correct, she has no cause of action. Given an ambiguity, this objection is a factor in statutory construction, but, of itself, it cannot create an ambiguity, or there could never be preemption. Finally, plaintiff says that the FDA's preemption regulation, 21 CFR § 808.1(d) conflicts with our result. When a statute is clear the agency interpretation must give way. Hillsborough County, 471 U.S. at 714-15.

A more troublesome issue is the claim labeled fraud.

FRAUD

> . . . Defendant Collagen Corporation fraudulently obtained FDA approval of the Zyderm PMA, product and labeling, which was a producing or proximate cause of damage and injury to Plaintiff. Defendant further acted to suppress the facts, blame injuries or other causes that its product (sic) prevent disclosure of the true risks.[6] Plaintiff has a case in point.

In Hurley v. Lederle Laboratories Division of American Cyanamid Co., 863 F.2d 1173 (5th Cir. 1988), the court, though agreeing with the district court that the FDA regulation with respect to defendant's vaccine labeling was intended to be preemptive, remanded. At issue was the same tension between protecting idiosyncratic individuals and the public health. Balancing these, the Court concluded,

> [T]his issue should be presented to the jury in the form of special interrogatories, questioning whether and what information the manufacturer withheld from the FDA, if any, and whether possession of this information would have materially altered the content of the FDA's warning. This special procedure is justified by the federal interest in encouraging manufacturers to produce vaccines, in that those manufacturers need some assurance that if they follow certain prescribed procedures, such as including an FDA-approved warning, they are complying with the law.

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[6] As in the original complaint, plaintiff sought treble damages. Though not mentioned, presumably this demand involved Mass. G.L. c. 231, § 85J, that awards treble damages in certain cases of "deceit or fraud." We do not read it, however, as limiting the scope of plaintiff's claims.

Id. at 1180. With respect, one may wonder how "encouraging" manufacturers would view the ruling.[7] Rather, we side with the later case of Papas v. Upjohn Co., 926 F.2d 1019 (11th Cir. 1991), where the court said, at 1026 n.8,

> To the extent that Hurley purports to recognize an exception to federal preemption of common law tort labeling claims when the federal statute involved explicitly prohibits state regulation of labeling and the federal agency has received incomplete information from the manufacturer, we reject its holding at least as applied to FIFRA-regulated pesticides. Given the FIFRA regulatory scheme, it would be up to the EPA -- not a jury -- to determine first (1) whether the information provided was complete or inaccurate; (2) whether the omitted information is significant enough to mandate a change of label; and (3) how, if at all, the label should be corrected.

To prove fraud, plaintiff must show causality. Surely, where the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision this would impose a state requirement "which is different from, or in addition to, any requirement applicable . . . the device." 21 U.S.C. § 360k(a). In addition to running afoul of the general principle against implying personal cause of action, Royal Bus Group, Inc., v. Realist, Inc., 933 F.2d 1056 (1st Cir. 1991), plaintiff would be breaching the federal dyke in the absence of its keeper.

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[7] Indeed, we are reminded of the observation that the British hanged a negligent admiral "pour encourager les autres." Voltaire, Candide, Ch. 23

Panas has been vacated and remanded for further consideration in light of Cipollone, 112 S. Ct. 2608, but we do not believe this to be a reversal on that point. Our position is consistent with Cipollone, that did not preempt fraud found to be outside the communication targeted by the regulation.[8] 112 S. Ct. at 2623-24.

[8] Plaintiff similarly presents a claim for misrepresentation, both to the public and to plaintiff's physician. As the record shows no statements to the public or physicians that go beyond those approved by the FDA, this claim collapses into that of fraud on the FDA.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANE KING,
Plaintiff

Civil Action
No. 90-12718-MA

vs.

THE COLLAGEN CORPORATION,
Defendant

MEMORANDUM AND ORDER

Mazzone, D.J. February 3, 1992

This is an action to recover damages for personal injuries allegedly incurred by the plaintiff as a result of receiving a dose of collagen implant manufactured by the defendant. She brings claims of negligent testing, manufacture and sale of the Collagen implant; breach of warranty of merchantability; and the sale of personal property by deceit or fraud, M.G.L. c. 231, § 85J. The matter is before me on the defendant's motion for summary judgment. The record is complete. The sole issue presented is whether the claims presented by the plaintiff are pre-empted by the Medical Device Amendment to the Food, Drug & Cosmetic Act, 21 U.S.C. §§ 360 c, et seq., and the regulations promulgated thereunder.

After careful review of the record and the relevant case law, I am persuaded by the clear, cogent analysis and careful reasoning presented by Chief Judge James DeAnda in Jennifer Stamps v. Collagen Corporation, Memorandum Opinion, Civil Action No. H-90-2242, U.S.D.C., S.D. Texas (October 11, 1991), (appeal pending).

I do not believe I can add anything to the discussion. That opinion addresses all of the issues presented here, including the plaintiff's allegations that the defendant's conduct was fraudulent. There are no factual issues in dispute. I conclude that the implants in this case are subject to the specific, detailed requirements of the Food, Drug and Cosmetic Act and, therefore, the plaintiff's claims are pre-empted. See also Moore v. Kimberly-Clark Corp., 867

F.2d 243 (5th Cir 1989) and Tarallo v. Searle Pharmaceutical, Inc., 704 F. Supp. 653 (D.S.C. 1988).

Accordingly, the defendant's motion for summary judgment is allowed.

SO ORDERED.

s/ A. David Mazzone
United States District Judge

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 92-1278

JANE KING
Plaintiff, Appellant

v.

THE COLLAGEN CORPORATION
Defendant, Appellee.

Before

Torruella, Circuit Judge
Aldrich and Campbell, Senior Circuit Judges

ORDER OF COURT

Entered: February 3, 1993

Plaintiff's petition for rehearing, that shows extraordinary disregard of our Internal Operating Procedures X, "Petitions...are not to be used for reargument of an issue previously presented," is denied.

By the Court

FRANCIS P. SCIGLIANO, CLERK.

By_____
Chief Deputy Clerk

[cc: Messrs. Lynch, Hanby, Essmyer, Leghorn, Wacheler, Redden, Webb and Ms. Allinger]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regualtion of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any rpovision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under the act. Under

section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to adevice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in National Women's Health Network, et. al. v. A.H. Robins Company, Inc., No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injuctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachussets or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures